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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,310	07/01/2003	Ryoichi Hashida	3462.1004-000	3981
21005	7590	01/27/2005	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			GALVEZ, JAMES JASON	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/611,310

Applicant(s)

HASHIDA ET AL.

Examiner

J. Jason Galvez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 4-30 and 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/04, 11/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group 1 in the reply filed on  
5 12/02/2004 is acknowledged. Pending claims are claims 1-53. Non-elected  
claims are claims 4-30 and 32-53. Accordingly, claims 1-3 and 31 are  
considered for examination.

### ***Priority***

10 Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d),  
which papers have been placed of record in the file. However, it is noted that no  
English translation of the foreign priority document has been supplied. Should  
Applicant need to rely on the foreign priority document submitted a translation  
would be required.

15

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 6/17/2004 and  
11/22/2004 is acknowledged and has been only partially considered. Applicant  
has not supplied a number of references cited in the IDS filed on 11/22/2004.

20 Accordingly, these references have not been considered.

***Specification***

The use of the trademarks PE BIOSYSTEMS (p. 16 AND 40), CLONTECH (p. 28), STRATAGENE (p. 28), BIACORE (p. 30), PHARMACIA (p. 30, 38), HITACHI (p. 37), AMERSHAM (p. 38), QIAGEN (p. 39), and  
5 AFFYMETRIX (p. 39) have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Applicant is strongly encouraged to review and correct the instant application regarding the misuse of trademarks.

Although the use of trademarks is permissible in patent applications, the  
10 proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

15 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make  
20 and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one  
25 skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state  
5 of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims are drawn to a method of testing for “an allergic disease” and  
10 in particular, “atopic dermatitis”. Claims 1 and 2 are drawn to allergic diseases and encompass many diseases that Applicant has not considered. For example, would the method claimed be effective for testing against such allergic diseases as seasonal allergies or pet dander? Furthermore, would there be any benefit or use of such tests directed to the mentioned allergic diseases since routine tests  
15 already exist and are used for these common allergic conditions.

Claims 3 and 31 are drawn to a specific allergic disease, “atopic dermatitis”. The specification is not enabled for the claimed method because even though Applicant recites that TR3 is “significantly enhanced” in atopic dermatitis samples (p. 44: lines 1-5) Applicant also presents conflicting data. For  
20 example, Table 7 on page 46 shows data using parametric and nonparametric statistical analysis with p-values that do not reach statistical significance (p-value= 0.0533). A p-value above 0.05 is indicative of a finding that is not significant. Furthermore, it appears that Applicant has excluded or did not

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perform the same statistical analysis on all the groups. It is apparent that statistical analysis can be performed on all of the groups with all of the different methodologies included in Table 7 since all the groups were analyzed under nonparametric multiple comparisons using a Dunnett test. Statistical analysis  
5 requires numbers, or raw data, which was available for nonparametric multiple comparisons using a Dunnett test and therefore should have been available for the other statistical measures.

Claims 1 and 3 are drawn to a diagnostic method whereby protein expression is measured. Even if the invention were enabled for a diagnostic  
10 assay measuring specific gene levels it would not be enabled for a diagnostic method directed to measuring specific protein levels. The diagnostic method disclosed in the specification described and showed results, although conflicting, relating to gene expression not protein expression. It is well known in the art that gene expression is not an accurate predictor of protein expression (Haynes et al.,  
15 Electrophoresis 1998, Vol. 19(11): pp. 1862-1871, esp. p. 1863: section 2.1). Therefore, the method disclosed is not enabled for a diagnostic method using protein expression as an outcome measure.

For the reason set forth, without further guidance a person of ordinary skill in the art would not be able to make and/or use the invention as claimed without  
20 undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a correlation step. The method claimed recites "comparing the expression level",

5 however there are no specific guidelines for the comparison in the method. The method should include how the comparison step relates to the method. For example, are positive results of the method identified by an upregulation or downregulation of specific genes?

10

**Conclusion**

NO CLAIMS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D.** whose telephone number is **571-272-2935**. The examiner can normally be reached Monday

15 through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an

20 application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about

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the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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JJG

10 1/24/2005

  
JANET ANDRES  
PRIMARY EXAMINER